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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,737	02/03/2004	David S. Burt	484112-410D1	4042

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,737	BURT ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *March 5, 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed March 27, 2007 in response to the Office Action of September 27, 2007 is acknowledged and has been entered. Claims 9, 10, and 11 are canceled. Claims 1, 7, 8, and 12 have been amended. New claims 13-21 have been added. Rejections of canceled claims 9, 10, and 11 under 35 U.S.C. 112, first paragraph, 102(b) and 103(a) are moot. Claims 1-8, and 12-21 are under examination.

Information Disclosure Statement

Applicant's IDS form 1449, filed March 5, 2007 is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1-8, and 12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to elicit an immune response comprising administering an influenza vaccine comprising hemagglutinin antigen, does not reasonably provide enablement for a method comprising administering an influenza vaccine comprising any one influenza antigen **is withdrawn** in view of Applicant's amendment.

Applicant amended the claims to recite the enabled embodiment such as influenza HA antigen.

New Rejection

Claims 1-8, and 12-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a ratio of proteosome to influenza HA antigen such as 2:1, 4:1, and 8:1, does not reasonably provide enablement for a method comprising administering of proteosome and influenza HA antigen in any other ratio that is greater than 8:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The claims encompass using any ratio of proteosome to influenza HA antigen that is greater than 2:1. In other words the current claims encompass a proteosome to influenza HA antigen in ratios such as for example 100:1. The instant specification provides examples of using influenza vaccine comprising hemagglutinin (HA) formulated with proteosome, wherein the proteosome to influenza HA antigen ratios are 2:1, 4:1, and 8:1 (see Example 11). The

specification does not provide examples wherein the proteosome to influenza HA antigen ratio is greater than 8:1. The current claims encompass an indefinite ratio of proteosome to influenza HA antigen. The skilled artisan would question whether any unlimited ratio of proteosome to influenza HA antigen could be useful for the purposes of the current invention. Example 13 of the specification discusses successful formation of proteosome and influenza HA antigen complexes using ratios such as 4:1 and 8:1. The skilled artisan would question whether the proteosome and influenza HA antigen complexes could be formed in the ratios higher than 8:1, simply because the overwhelming amounts of proteosomes could hinder formation of proteosome and HA antigen complexes. Thus the instant specification does not provide an enabling disclosure for practicing the method of eliciting an immune response using proteosome and HA antigen ratios greater than 8:1.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the method for eliciting an immune response using proteosome and HA antigen ratios greater than 8:1, that one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether proteosome and HA antigen ratios greater than 8:1 could be successfully used in the claimed methods.

Claims 1-8, and 12-21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method for eliciting an immune response against influenza in a subject, and a method for treating infection in an animal comprising administering influenza

vaccine of viral antigen formulated with proteosome preparation, wherein the proteosome and HA antigen ratio is greater than 2:1.

The metes and bound of the proteosome and HA antigen ratio greater than 2:1 cannot be determined because the recitation of ratio greater than 2:1, does not set an upper limit on the claimed ratio. Correction and clarification is required.

Claim Rejections - 35 USC § 102

Rejection of claims 1-4, 6-9 and 12 under 35 U.S.C. 102(b) as being anticipated by Levi et al. (Vaccine, 1995, IDS of 7/22/2005) **is withdrawn** in view of Applicant's amendment.

Applicant amended the claims to recite ratio of proteosome and influenza HA antigen is 2:1 or greater. The recitation of "greater" is interpreted as the number for proteosome increases wherein the number for influenza HA antigen remains constant. Levy does not anticipate the current claims because Levy discloses proteosome and influenza HA antigen ratio such as 1:4. On the contrary to the current invention Levy used more influenza HA antigen than proteosome.

Claim Rejections - 35 USC § 103

Rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Levi et al. (Vaccine, 1995, IDS of 7/22/2005) as applied to claims 1-4, 6-12 above, and further in view of Fynan et al. (International Journal of Immunopharmacology, 1995) **is withdrawn** in view of Applicant's amendment.

Applicant amended the claims to recite ratio of proteosome and influenza HA antigen is 2:1 or greater. The recitation of "greater" is interpreted as the number for proteosome increases wherein the number for influenza HA antigen remains constant. Levy does not anticipate the

current claims because Levy discloses proteosome and influenza HA antigen ratio such as 1:4. On the contrary to the current invention Levy used more influenza HA antigen than proteosome

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.
6/11/07

/Stacy B. Chen/ 6-11-2007
Primary Examiner, TC1600